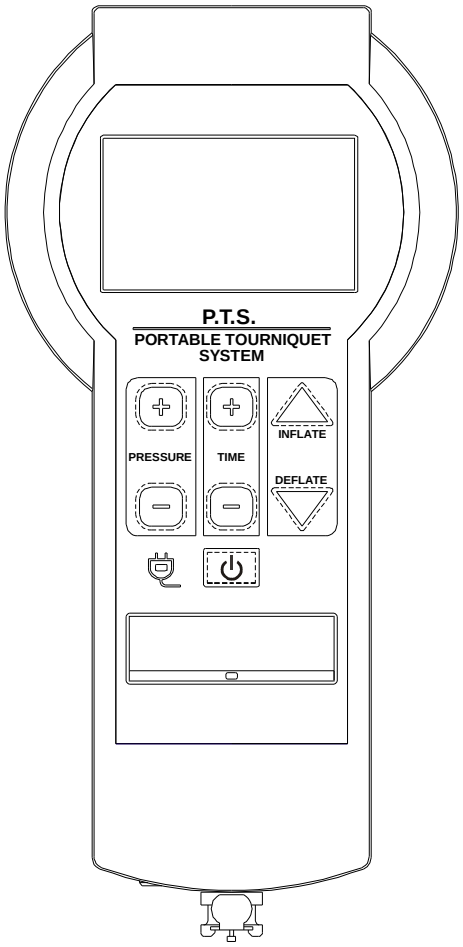
OPERATOR and MAINTENANCE MANUAL
DELFI P.T.S. PORTABLE TOURNIQUET SYSTEM



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LIMITED ONE YEAR WARRANTY (U.S.A. only)

SCOPE OF WARRANTY

Delfi Medical Innovations Inc. ('Delfi') warrants the P.T.S. Portable Tourniquet System ('product') for one year from date of purchase. During the warranty period, Delfi will repair or replace, at its option, any product which is defective in materials or workmanship or which fails to meet the published specification for that model. This Limited Warranty is made only to the original purchaser of the product and is non-transferable. The remedies described in the Limited Warranty are the exclusive remedies for breach of warranty. THIS WARRANTY SHALL NOT APPLY TO ANY PRODUCT WHICH HAS BEEN ALTERED, MODIFIED, DISASSEMBLED OR SERVICED BY ANYONE OTHER THAN DELFI STAFF IN ANY WAY, OR WHICH HAS BEEN SUBJECTED TO MISUSE OR ABUSE.

DISCLAIMER OF IMPLIED WARRANTIES

The foregoing Express Limited Warranty is given in lieu of any and all other express or implied warranties. DELFI MAKES NO OTHER WARRANTIES INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

LIMITATION OF REMEDIES

In no case shall Delfi Medical Innovations Inc. be liable for any special incidental or consequential damages whether based on breach of warranty or other legal theory. Some states do not allow limitations on warranties or on remedies for breach in certain transactions. In such states, the limits in this paragraph and the preceding paragraph do not apply.

WARRANTY CLAIMS

In the event of a warranty claim within the warranty period please take the following steps:

1. Notify Customer Service Department, Delfi Medical Innovations Inc. at 800-933-3022. Please provide details about the nature of the problem and include the product serial number. Upon receipt of this information, Delfi will provide a date for service or a return shipping authorization.
2. Upon receipt of the shipping authorization, forward the equipment, freight prepaid, to the location specified in the shipping authorization.

Your compliance with these steps will help assure that you receive prompt warranty service for your product.

WARRANTY (OUTSIDE U.S.A.)

Please contact Delfi for warranty information.

Unit Serial Number _____

AC Power Supply Serial Number _____

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FIGURES and TABLES:

SECTION 1.0: DELFI PORTABLE TOURNIQUET SYSTEM (P.T.S.) GENERAL INFORMATION

NOTE: Use this tourniquet system according to the policies in your practice setting. The following information on intended use, precautions, contraindications, and adverse effects are offered as a guide to assist in this process.

1.1 INTENDED USE

The Delfi Portable Tourniquet System (P.T.S.) is intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremity during surgical procedures on that extremity. Tourniquets are generally used for operations lasting less than 90 minutes. Tourniquets have been found useful in producing a bloodless operation field in surgical procedures involving the extremities including:

- Reduction of certain fractures
- Tumor and cyst excisions
- Arthroscopy of certain joints
- Bone grafts
- Subcutaneous fasciotomy
- Tendon repair
- Kirschner wire removal
- Knee joint replacements
- Replacement of finger joints
- Amputations
- Nerve injuries
- Total wrist joint replacement

WARNING: Do not use tourniquet cuffs to control the distal flow of CO_2 or any other gases used as a distention media. Tourniquet cuffs have not been evaluated for safety or effectiveness in controlling gas flow beyond the surgical site during arthroscopic insufflation procedures. Possible effects of using a tourniquet cuff in this manner include serious subcutaneous emphysema proximal to the cuff.

1.2 CONTRAINDICATIONS

Refer to the medical literature for possible contraindications to tourniquet use. A partial list is provided below, however in every case the final decision to use a tourniquet rests with the attending physician.

- Open fractures of the leg
- Severe crushing injuries
- Post-traumatic lengthy hand reconstruction
- Diabetes mellitus
- Severe hypertension
- Elbow surgery (where there is concomitant excess swelling)
- Skin grafts in which all bleeding points must be readily distinguished
- Compromised vascular circulation, e.g., peripheral artery disease
- Sickle cell disease or trait (relative contraindication, see PRECAUTIONS IN USE).
- Secondary or delayed procedures after immobilization.

1.3 PRECAUTIONS IN USE

- The tourniquet system must be kept well calibrated and in operable condition. Accessories should be checked regularly for leaks and other defects.
- The tourniquet cuff must never be punctured; therefore towel clips used near the system must be handled with special care.
- Cuffs with inner rubber bladders must be completely enclosed by the outer envelope to preclude ballooning and possible rupture of the bladder. Cleaning and assembly instructions of the cuff manufacturer should be followed carefully.
- Do not use an elastic bandage for exsanguination in cases where this will cause bacteria, exotoxins, or malignant cells to spread to the general circulation, or where it could dislodge thromboemboli that may have formed in the vessels.
- The tourniquet cuff must be applied in the proper location on the limb. Tourniquet pressure and the time the tourniquet is inflated on the limb should both be minimized. There is additional potential risk to superficial nerves in unprotected areas; never apply a tourniquet over an area where major nerves may be directly compressed against bone (eg. peroneal nerve near the proximal head of the fibula). Never apply a tourniquet over the joints of the limb. Do not readjust an already inflated cuff by rotating it because this produces shearing forces which may damage the underlying tissue. Prolonged ischemia may lead to temporary or permanent damage to tissues, blood vessels, and nerves.

- Prolonged tourniquet time can also produce changes in the coagulability of the blood with increased clotting time. Always minimize tourniquet time.
- Tourniquet paralysis may result from excessive pressure. Insufficient pressure may result in passive congestion of the limb with possible irreversible functional loss. Always use the minimum effective tourniquet pressure, as described in the medical literature.
- Inflation should be done rapidly to occlude arteries and veins as near simultaneously as possible.
- Careful and complete exsanguination reportedly prolongs pain-free tourniquet time and improves the quality of Intravenous Regional Anesthesia (Bier Block anesthesia). In the presence of infection and painful fractures, after the patient has been in a cast, and in amputations due to malignant tumors, exsanguination before tourniquet application may be done without the use of an elastic bandage by elevating the limb for 3 to 5 minutes.
- In case of failure, the tourniquet cuff must be fully deflated and the limb exsanguinated again before reinflation. Reinflation over blood-filled vasculature may lead to intravascular thrombosis.
- Tourniquet users must be familiar with the inflation-deflation sequence when using two tourniquet cuffs and two P.T.S. units together for IVRA (Bier Block anesthesia), so that the wrong tourniquet will not be released accidentally.
- Test for hemoglobin type and level before using a tourniquet on patients with sickle-cell anemia. When the tourniquet is used for these patients, the limb should be carefully exsanguinated and the PO_2 and pH should be closely monitored.
- Select the proper cuff size to allow for the overlap recommended by the cuff manufacturer. Too much or too little overlap may cause cuff rolling and telescoping, unexpected release of the cuff from the limb, inability to maintain a bloodless field at normal pressures, and/or undesired pressure distribution on the limb.
- The skin under the tourniquet cuff must be protected from mechanical injury by smooth, wrinkle-free application of the cuff. If the tourniquet cuff is applied over any material that may shed loose fibers (such as Webril) the fibers may become embedded in the contact closures and reduce their effectiveness. Follow the cuff manufacturer's recommendations for limb protection material under the cuff. In general, a limb protection sleeve designed specifically for the cuff provides the best protection.
- If skin preparations are used preoperatively, they should not be allowed to flow nor collect under the cuff where they may cause chemical burns.
- Whenever the tourniquet cuff pressure is released, the wound should be protected from blood surging back by applying pressure dressings and, if necessary, elevating the limb. Transient pain upon tourniquet pressure release can be lessened by elevation of the limb. If full color does not return within 3 to 4 minutes after release, the limb should be placed in a position slightly below body level.
- **The deflated cuff and any underlying limb protection material should be completely removed as soon as tourniquet pressure is released. After the cuff has been fully deflated and removed from the patient, the unit can be set to STANDBY. Even the slightest impedance of venous return may lead to congestion and pooling of blood in the operative field.**
- Whenever IVRA (Bier Block anesthesia) is used, it is recommended that the tourniquet remain inflated for at least 20 minutes from the time of injection.

1.4 ADVERSE EFFECTS

A dull aching pain (tourniquet pain) may develop throughout the limb following use. Stiffness, weakness, reactive hyperemia, & skin discolouration may also occur to some degree in all patients after tourniquet use.
Pathophysiologic changes due to pressure, hypoxia, hypercarbia, and acidosis of the tissues occur and become significant after about 1 1/2 hours of tourniquet use.
Symptoms of tourniquet paralysis are motor paralysis and loss of sense of touch, pressure, and proprioceptive responses.
Intraoperative bleeding may be caused by:

- The slight impeding effect exerted by an unpressurized cuff (and its limb protection material or padding, if used), which prevents venous return at the beginning of the operation,
- Blood remaining in the limb because of insufficient exsanguination,
- Inadequate tourniquet pressure, or slow inflation and deflation, all if which allow arterial blood to enter while preventing venous return,
- Blood entering through the nutrient vessels of the long bones, such as the femur or humerus.

SECTION 2.0: P.T.S. INSTALLATION AND OPERATING INSTRUCTIONS

2.1 SPECIFICATIONS

2.1.1 POWER REQUIREMENTS

Mains Line Voltage (AC Powered Mode):
90-264 VAC. 47/63 Hz.
Line current:
< 0.5 A RMS at 90 VAC input.
Input Power:
20 watts maximum.
AC Power Adaptor:
Use only supplied AC adapter / power cord assembly Delfi REF 4-2100-013.
AC Power plug: (North America)
Hospital grade, 3 prong straight blade, 15 amp.
Battery Type:
Sealed 4.8V nickel-metal-hydride (NiMh) pack, 1800 milliamp hours
Use only Delfi REF 4-2100-017 battery pack.
Battery Recharge Time:
8.0 hours (typical).

2.1.2 PERFORMANCE

Cuff Pressure Range:
50-475 mmHg, 5 mmHg increments.
Pressure Accuracy:
+/- 5 mmHg.
Pressure Regulation:
+/- 10 mmHg of set point (10 second average under non transient conditions).
Time Alarm Set Point Range:
0-240 minutes.
Timer Accuracy:
0.1% of elapsed time.
Inflation Rate:
34 inch cylindrical cuff applied to a 30 inch thigh inflates to 350 mmHg in less than 20 seconds.
Deflation Rate:
34 inch cuff applied to a 30 inch thigh deflates to less than 10 mmHg in less than 25 seconds.

2.1.3 SIZE

Height: 240 mm (9.45 inches)
Width: 116 mm (4.57 inches)
Depth: 50 mm (1.97 inches)
Weight: 500 g (17.5 oz)

2.1.4 ENVIRONMENTAL

Operating temperature: 10 to 40 °C (15 to 105 °F)
Storage temperature: -20 to 40 °C (-4 to 105 °F)
Humidity: Max 80 % non-condensing

2.2 INITIAL INSPECTION

Unpack the P.T.S. upon receipt and inspect the unit for any obvious damage that may have occurred during shipment. We recommend that this inspection be performed by a qualified biomedical engineer or other person thoroughly familiar with electronic medical devices. If the unit is damaged, notify the carrier and Delfi immediately. If the initial inspection results are satisfactory, a functional and calibration check should be performed after an 8-hour charge. The attention label covering the pressure/time display window button may be removed and discarded after the initial 8 hour charge.

2.3 CONTROLS, INDICATORS, DISPLAYS, AND CONNECTORS

Refer to Figure 2.1 for the locations of the unit's controls, indicators, displays and connectors described below:

1. 'ON/STANDBY' Button

Turns the unit on or sets the unit to standby. In standby mode (powered off), the power to all instrument functions (i.e. inflation, deflation, etc.) is off, but power continues to supply the battery charging circuitry whenever AC power is present. This button will not set the unit to standby when there is pressure in the cuff. Ensure the cuff is fully deflated, and the cuff and limb protection material have been removed from the patient prior to setting the unit to standby.

2. 'PRESSURE + ' Button

Displays and increases the pressure set point in mmHg. Momentarily depressing the 'PRESSURE + ' button will display the pressure set point with a trailing asterisk for 2 seconds. For example, if the set point was 250 mmHg and the user pressed and released the 'PRESSURE + ' button, the display would show "250* " for 2 seconds, then revert to the current cuff pressure (displayed without the trailing asterisk). If the 'PRESSURE + ' button is held for more than 1 second, the unit will begin increasing the pressure set point first by 5 mmHg then by 10 mmHg increments. If the cuff is inflating or inflated, cuff pressure will change to the new pressure set point.

3. 'PRESSURE – ' Button

Displays and decreases the pressure set point, as described above for the 'PRESSURE + ' button.

4. 'TIME + ' Button

Displays and increases the time limit set point in minutes. Momentarily depressing the 'TIME + ' button will display the time limit set point with a trailing asterisk for 2 seconds. For example, if the time limit set point was 60 minutes and the user pressed and released the 'TIME + ' button, the display would show "60* " for 2 seconds, then revert to the current tourniquet elapsed time. If the 'TIME + ' button is held in for more than 1 second, the unit advances the time limit set point first by 5 minute then by 10 minute increments.

5. 'TIME – ' Button

Displays and decreases the time limit set point, as described above for the 'TIME + ' button.

6. 'INFLATE' Button

Inflates the cuff to the pressure set point and starts the elapsed time monitor. Momentarily depressing the 'INFLATE' button immediately begins rapid inflation of the cuff.

7. 'DEFLATE' Button

Deflates the cuff and stops the elapsed time monitor. To prevent accidental deflation of the cuff, the 'DEFLATE' button has a delay and must be pressed and held for approximately 2 seconds before the unit will deflate the cuff. A short tone is sounded after the 2 second delay to indicate that deflation has started and the user may then release the 'DEFLATE' button. If the user momentary presses then releases the 'DEFLATE' button, nothing happens. If the user releases the 'DEFLATE' button any time after deflation has begun, the cuff continues to deflate to zero pressure.

8. Pressure and Time Display

During normal operation with no buttons being pressed, the top line of the pressure and time display shows the current sensed cuff pressure in mmHg, and the lower line shows the number of minutes the cuff has been inflated (tourniquet time). Anytime a trailing asterisk (*) appears after the pressure or time value, the value being displayed is the set point. Under certain conditions the pressure and time displays may show error codes or alarm messages. The tourniquet time can be reset to zero by pressing the 'TIME+ ' and 'TIME- ' buttons simultaneously only when the cuff is deflated. If the cuff is deflated and then reinflated without zeroing the tourniquet time display, the tourniquet time restarts from the last value, thereby displaying the cumulative tourniquet time. Switching the P.T.S. to standby also resets the tourniquet time to zero.

9. Message Display

When alarm conditions are present, the corresponding words are displayed and will remain displayed until the alarm condition is corrected, as long as sufficient power is available. When operating on battery power the battery indicator symbol is shown (see below).

10. AC Power Indicator Light

The green AC power indicator light is illuminated at all times when AC power is plugged in to the P.T.S., both in on and standby modes. Note that the AC power indicator light remains off at all times when there is no AC power connected to the P.T.S., even during the startup routine.

11. Alarm Indicator Light

The red alarm indicator light is illuminated when any alarm condition exists. The alarm indicator will remain illuminated until the alarm condition is corrected, as long sufficient power is available.

12. Battery Indicator Symbol

The battery indicator symbol in the center of the message display (see above) is visible when the P.T.S. is on and operating on battery power (AC power not connected). When all six segments inside the battery symbol are darkened, the battery has a full charge. Reducing numbers of darkened segments and low battery alarm conditions (see Table 2.1) progressively indicate decreasing battery capacity and need for recharging. The battery indicator symbol disappears when AC power is connected to the P.T.S.

13. Hose Connector

The hose assembly (see below) leading to the tourniquet cuff plugs in to the P.T.S. unit at the hose connector. The hose connector is a positive locking type that makes an audible ‘click’ when properly connected.

14. Hose Assembly

One hose assembly is supplied with each P.T.S. unit. The male positive locking connector plugs in to the hose connector on the P.T.S. unit (see above). The female end attaches to the tourniquet cuff. The P.T.S. is designed, tested, and recommended for use with Delfi and other single port cuffs having Positive Locking Connectors only. Use the supplied hose assembly only. An adapter is provided with the P.T.S. unit for connection to calibration equipment.

15. AC Power Receptacle

The AC power receptacle is located beside the hose connector. The P.T.S. is designed for use with the supplied AC power supply (see below) only; do not use any other type of connection to AC power.

16. AC Power Supply

An AC power supply adapter is supplied with every P.T.S. unit. It is a sealed unit designed specifically for the P.T.S. Contact Delfi if your power supply needs service or replacement. Plug the locking connector on the AC power supply cord into the AC power receptacle on the P.T.S. unit (see above), and plug the AC power cord into a power outlet (see below) whenever using the unit where AC power is easily accessible. The AC connector can only be inserted one way into the the AC power receptacle on the P.T.S. unit, and locks with an audible ‘click’ when properly connected. To disconnect, press the black button on the connector and pull it out.

17. AC Power Cord

An AC power cord with a hospital grade plug is supplied with every P.T.S. unit. Plug the socket end of the cord into the AC power supply and the plug end into an AC power outlet.

Figure 2.1: P.T.S. Controls, Indicators, Displays, and Connectors

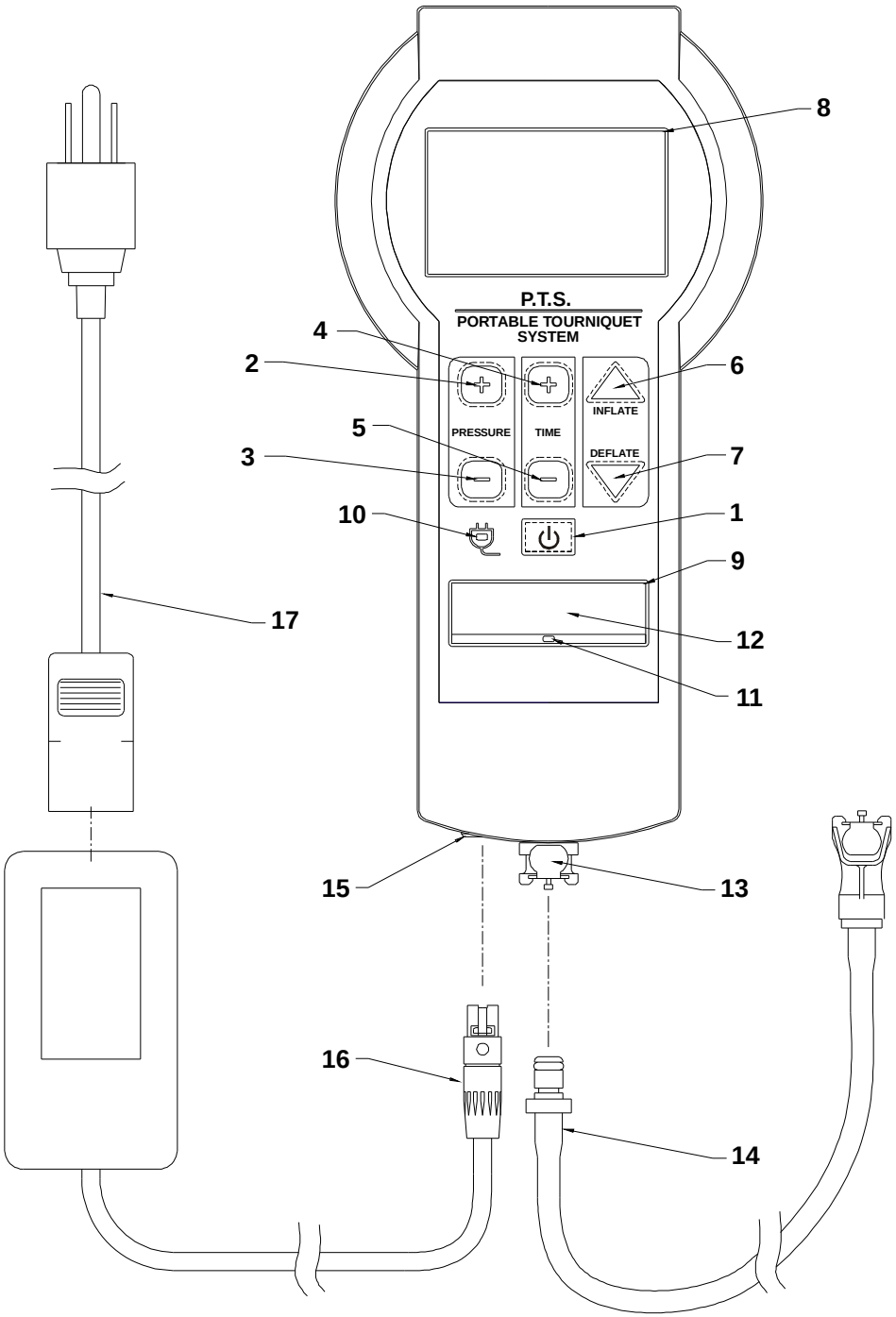


Figure 2.2: P.T.S. Pressure and Time Display Detail

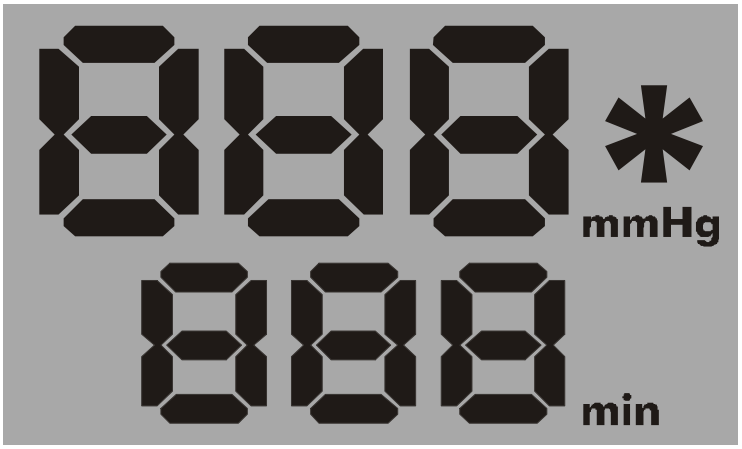
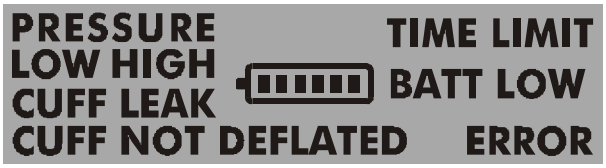


Figure 2.3: P.T.S. Message Display Detail



2.4 INITIAL SETUP

During shipping and storage, the unit's battery could become weak. Prior to initial use, the unit must be plugged into AC power using the AC power supply and cord assembly until the battery is fully charged. This initial charge should take no more than 8 hours. The battery must be fully charged before any initial use, including any calibration checking procedures, initial checks, or tests performed by biomedical engineering at your facility.

WARNING: Use only the Delfi REF 4-2100-013 AC power supply and cord assembly supplied with your P.T.S. Do not use any other AC power supply or cord. Use of an improper power supply may cause irregular operation that could be hazardous to the patient and/or user, and may permanently damage the P.T.S. unit.

CAUTION: Avoid exposing the AC power supply to liquids. Do not immerse in fluid. Do not allow the AC power supply to lie on the floor where pooling of liquids may occur. Clean by damp cloth (alcohol or mild detergent wipe) only. The AC power supply is resistant to occasional splashing or dripping of fluids, but is not fluid-tight. If immersed in or exposed to excessive amounts of liquids, the AC power supply may fail and may pose an electrical shock hazard.

WARNING: Use battery packs supplied by Delfi only. Do not use any other batteries. Use of an improper battery pack may cause irregular operation that could be hazardous to the patient and/or user, and may permanently damage the P.T.S. unit.

2.5 FUNCTIONAL AND CALIBRATION CHECK

Each P.T.S. unit is fully tested before shipping. However, the following functional and calibration checks should be performed by the user before the first clinical use of the P.T.S. to ensure that it has not been damaged in shipping. After charging the battery as described above, the unit shall produce the results explained in the following steps exactly as indicated. Failure to do so indicates that a problem may exist and the device is not to be used until necessary repair or calibration has been made.

2.5.1 AC POWER CONNECTION AND INDICATOR:

Connect the AC power plug to a properly polarized and grounded power source with voltage and frequency characteristics compatible with the specifications listed in Section 2.1. Observe that the green AC power indicator light turns on.

2.5.2 POWER-UP SEQUENCE AND SELF-TESTS:

Power up the unit by pressing the ‘ON/STANDBY’ button and observe the following (the P.T.S. may be plugged in to AC power or not for the remaining tests):

a) All display segments and symbols in the pressure and time display and the message display (as shown in Figures 2.2 and 2.3) illuminate, the red alarm indicator light illuminates, and the alarm tone sounds for 2 seconds. All displays and tones then shut off for 0.5 seconds, then the cycle repeats. Note that if AC power is not connected, the green AC power indicator light does not come on at any time, and if AC power is connected it remains on constantly.

b) The pressure display shows "CAL" for approximately 2 seconds. During this time the unit is self-testing specific pressure sensing calibration parameters.

c) "0" is displayed for both pressure and time in the pressure and time display after the startup routine is complete. If numbers other than zero are shown in either display, the unit should be calibrated.

2.5.3 PRESSURE SET POINT ADJUSTMENT:

a) Momentarily press the ‘PRESSURE + ‘ button and release (within 1 second). The pressure display reads "250* " (the default pressure set point) for 2 seconds. Note that the trailing asterisk indicates that the pressure displayed is a set point, not the current cuff pressure. The pressure display then returns to “0”.

b) Press and hold the ‘PRESSURE + ‘ button. The pressure display should read "250* ", and after 1 second begin increasing in 5mmHg and then by 10 mmHg increments to the maximum pressure set point of “475* “ mmHg.

c) Release the ‘PRESSURE + ‘ button. Within 2 seconds, the pressure display returns to “0”.

d) Momentarily press the ‘PRESSURE – ‘ button and release (within 1 second). The pressure display reads "475*" (the new pressure set point) for 2 seconds. The pressure display then returns to “0”.

e) Press and hold the ‘PRESSURE – ‘ button. The pressure display should read "475*", and after 1 second begin decreasing in 5mmHg increments and then by 10 mmHg to the minimum pressure set point of “50*“ mmHg.

f) Release the ‘PRESSURE – ‘ button. Within 2 seconds, the pressure display returns to “0”.

2.5.4 TIME LIMIT SET POINT ADJUSTMENT:

a) Momentarily press the ‘TIME + ‘ button and release (within 1 second). The time display reads "60* " (the default time limit set point) for 2 seconds. Note that the trailing asterisk indicates that the time displayed is a set point, not the current elapsed time that the cuff has been inflated. The time display then returns to “0”.

b) Press and hold the ‘TIME + ‘ button. The time display should read "60* ", and after 1 second begin increasing in 5 minute and then by 10 minute increments to the maximum time limit set point of “240* “ minutes.

c) Release the ‘TIME + ‘ button. Within 2 seconds, the time display returns to “0”.

d) Momentarily press the ‘TIME – ‘ button and release (within 1 second). The time display reads "240* " (the new time limit set point) for 2 seconds. The time display then returns to “0”.

e) Press and hold the ‘TIME – ‘ button. The time display should read "240* ", and after 1 second begin decreasing in 5 minute and then by 10 minute increments to the minimum time limit set point of “5* “ minutes.

f) Release the ‘TIME – ‘ button. Within 2 seconds, the time display returns to “0”.

NOTE: Anytime a trailing asterisk (*) appears, the data being displayed is the set point. Set pressure and time will revert to the default pressure and time when the unit is powered off and powered up again.

2.5.5 CALIBRATION CHECK:

NOTE: Every P.T.S. unit is calibrated at the factory before shipping. The unit also self-tests specific calibration parameters upon power-up. Should a potential out of calibration condition be detected, the unit will display error messages (see Table 2.1). However even though the unit performs a self-test of calibration at every power-up, the following quantitative check is recommended prior to initial use, and at regular intervals according to the policies in your practice setting.

a) Connect the P.T.S. hose set to the P.T.S. unit, then connect the hose to a reference pressure gauge known to be accurate (e.g. manometer or calibrated gauge). If required, use the Positive Locking Connector to Luer adapter supplied with your P.T.S. unit to connect the end of the P.T.S. hose to the reference gauge.

b) Power up the unit by pressing the ‘ON/STANDBY’ button, set the pressure set point to 50 mmHg using the ‘PRESSURE – ‘ button and press the ‘INFLATE’ button.

c) Allow the pressure to stabilize. The pressure reading on the P.T.S. and the reference gauge should be within 5 mmHg of each other, and within 5 mmHg of the pressure set point of 50 mmHg.

d) Using the ‘PRESSURE + ‘ button to increase the pressure, repeat step 2.5.5(c) above for 250 mmHg and 475 mmHg.

e) Press and hold the ‘DEFLATE’ button for 2 seconds to deflate the unit. Disconnect the hose from the P.T.S. unit. The pressure display should decrease to 0 mmHg.

f) If any stablized pressure reading is off by more than 5 mmHg during the calibration check or the pressure display does not return to zero, the unit must be calibrated. See Section 3.3 below.

2.5.6 “PRESSURE LOW” and “CUFF LEAK” ALARM CHECK:

Connect the hose assembly and a cuff to the P.T.S. and press the ‘INFLATE’ button. The cuff inflates to the default pressure set point of 250 mmHg. Create a leak by partially detaching the hose from the unit while the cuff is inflated. Make the leak large enough that the pressure drops more than 15 mmHg below set point. The pump in the P.T.S. unit will start as the unit tries to maintain the set pressure. After the cuff pressure has been more than 15 mmHg below the set point constantly for more than 1 second, confirm that:

a) The pressure display flashes on/off;

b) “PRESSURE LOW” appears in the message display (“CUFF LEAK” may also appear);

c) The red alarm indicator light is illuminated;

d) The alarm tone sounds constantly.

Press the ‘PRESSURE + ‘, ‘PRESSURE – ‘, ‘TIME + ‘, or ‘TIME – ‘ button to silence the alarm tone. Confirm that the alarm tone restarts after 30 seconds. Stop the leak and confirm that the displayed pressure returns to the set point and stops flashing, the “PRESSURE LOW” (and “CUFF LEAK” if present) messages disappear, the red alarm indicator light turns off, and the alarm tone stops.

2.6 PRESSURE AND TIME DEFAULTS

Changing the default pressure set point and time limit set point values may only be done after power-up and before inflation of the cuff. To modify the default set points:

a) Adjust the pressure set point to the desired default value by pressing and holding the ‘PRESSURE + ‘ or ‘PRESSURE – ‘ buttons as required.

b) Adjust the time limit set point to the desired default value by pressing and holding the ‘TIME + ‘ or ‘TIME – ‘ buttons as required.

c) Momentarily press and release the ‘PRESSURE + ‘ and ‘PRESSURE – ‘ buttons simultaneously. The alarm tone sounds briefly, then the pressure and time set points appear (with trailing asterisk symbols) in the pressure and time displays to indicate that the new default values have been stored.

d) After about 2 seconds, the unit resumes normal operation.

e) The new default set point values will now be present every time the machine is turned on.

2.7 OPERATION

NOTE: The P.T.S. unit should be powered up at least once each day of use to ensure the self-test routine is performed regularly. The P.T.S. should be powered off and left plugged in to AC power when not in use.

a) Press the ‘ON/STANDBY’ button to turn the unit on. The unit will execute a self-check diagnostic test as described in Section 2.5.2 of this manual. Observe that all the display segments and the red alarm indicator light illuminate during the self-check as shown in Figs 2.2 and 2.3. Successful completion of the self-check indicates that the unit is ready for use.

WARNING: If a connected cuff is pressurized to 50 mmHg or more during power-up, the P.T.S. will assume that a surgical procedure is in progress, adopt the pressure sensed in the cuff as the new set point, and will automatically regulate the cuff at this pressure. To alert the operator of this condition, the unit will sound the alarm tone, illuminate the red alarm indicator light, flash the pressure display, and show "PRESSURE” in the message display. The operator should immediately check the pressure set point and readjust to the proper set point if necessary. The alarm will be cleared as soon as the set point is examined or adjusted (‘PRESSURE + ‘ or ‘PRESSURE – ‘ button pressed momentarily or pressed and held).

b) Connect the hose assembly and a single port cuff to the unit at the hose connector.

c) Select the appropriate tourniquet pressure and tourniquet time limit set points for the specific procedure, as specified by the surgeon. The default set points for pressure and time limit are retrieved from the

memory during power up and are active until the user adjusts them (see Sections 2.5.3 and 2.5.4). These default values can be modified by the user (see Section 2.6).

WARNING: In all cases it is essential to check the pressure and time limit set points and confirm that they are the desired values before inflating the cuff.

For each patient, tourniquet pressure required to occlude blood flow to operative site should be set to the minimum effective pressure. The minimum effective pressure depends on many factors, including the location of the cuff (upper or lower limb), the type of cuff and quality of fit to the limb, whether the limb is normal, hypertrophied, or obese, the patient's preoperative systolic pressure, and the maximum anticipated rise in systolic pressure during the procedure. Refer to the medical literature for current techniques for determining the minimum effective tourniquet pressure for each case.

d) Prepare the patient in accordance with your established procedures and cuff manufacturer's instructions. The precautions of Section 1 and the following are offered as a guide to assist in this process. In most cases a tourniquet cuff should be applied to the widest part of the limb to allow as much tissue as possible to lie between the cuff and any nerves or vascular structures susceptible to damage. The optimum positions are the upper arm and the proximal third of the thigh. In certain cases of fore-foot surgery, the tourniquet cuff can be applied around the calf or to the area proximal to the malleoli. For emergency surgery of the hand, a sufficiently small tourniquet may be selected by the surgeon for fitting around the forearm. Apply a leak-free tourniquet cuff smoothly without wrinkles The hose connections should be placed so that the hose will not be kinked when the limb is positioned for surgery. The viability of the skin and deeper tissues should be established prior to exsanguination of the limb and tourniquet inflation. Exsanguinate the limb by elevating it for a minimum of 2 minutes and wrapping it, distal to proximal, using an Esmarch, Martin, or elastic bandage. The bandage should come up approximately to 1 in. (2.5 cm) from the edge of the tourniquet cuff. The elastic bandage is removed following inflation of the cuff. If regional anesthesia is being used, the anesthetic agent or nerve block is then administered. The surgeon will determine:
    - When the tourniquet is to be inflated;
    - What pressure is applied;
    - How long the tourniquet is applied;
    - Whether to allow for intermittent aeration of tissue by deflating the cuff, and the duration of these aeration periods;
    - When to deflate and remove the tourniquet.

    Appropriate tourniquet time and the need for intermittent deflation of the cuff depend greatly on the patient's anatomy, age, and absence of vascular disease. In many operating rooms, it is customary to prominently note the time of inflation, and to warn the surgeon after a certain time has elapsed. This will allow the surgeon to assess the need for further tourniquet time.

e) Press the ‘INFLATE’ button when the cuff must be inflated. The unit will pressurize the cuff to the pressure set point and start the tourniquet time clock. If the unit cannot pressurize the cuff to within 15 mmHg of the set point in less than 45 seconds, a leak alarm will be sounded (see Table 2.1 for information about possible alarm conditions). The time display shows the tourniquet time, and the pressure display shows the current pressure in the cuff.

f) When the cuff must be deflated, press and hold the ‘DEFLATE’ button. After holding the button for 2 seconds, the alarm tone will sound briefly, the pressure display will show the falling pressure of the cuff, and the tourniquet time clock will stop and hold the display of the tourniquet time. **Remove the tourniquet cuff and any underlying limb protection material immediately following final cuff deflation**. The time of tourniquet cuff removal should be noted, and the circulation of the limb should be checked.

NOTE: The elapsed tourniquet time can be zeroed after the cuff is deflated by pressing and holding the ‘TIME+ ‘ and ‘TIME- ‘ buttons simultaneously. The alarm tone will sound briefly to indicate the time has been zeroed.

g) After the cuff has been removed, disconnect the cuff from the P.T.S. During normal use, the P.T.S. should not be set to standby if pressure is present in the cuff. Once the cuff has been properly deflated, removed from the patient and disconnected from the P.T.S., the unit can be set to standby.

2.8 ALARM CONDITIONS

There are a number of conditions for which the P.T.S. will produce visual and audible alarms. Those conditions, indications and appropriate actions are shown in Table 2.1. The appropriate actions indicated are based on the most probable causes and should only be used as a guide. Other causes of alarm conditions may indicate a need for other actions.

Table 2.1: Alarm Conditions

Condition	Description	Message display (steady)	Alarm tone	Pressure display	Time display	Action to silence alarm tone for 30 seconds	Action required to correct alarm condition
High Pressure above set point	The unit has detected high pressure in the cuff. High pressure is defined as pressure that is +15mmHg above the pressure set point continuously for more than 1 second.	PRESSURE HIGH	Constant	Current cuff pressure, flashing	Normal	Momentarily Press 'PRESSURE + ', 'PRESSURE – ', 'TIME + ', or 'TIME – '.	Press and hold 'PRESSURE + ' to adjust set pressure to within 15mmHg of sensed pressure OR Press and hold 'DEFLATE' for 2 seconds to deflate the cuff. Alarm will stop automatically whenever the unit can regulate the cuff to within 15 mmHg of the pressure set point.
Low Pressure below set point	The unit has detected low pressure in the cuff. Low pressure is defined as pressure that is 15mmHg below the pressure set point continuously for more than 1 second.	PRESSURE LOW	Constant	Current cuff pressure, flashing	Normal	Momentarily Press 'PRESSURE + ', 'PRESSURE – ', 'TIME + ', or 'TIME – '.	Press and hold 'PRESSURE – ' to adjust set pressure to within 15mmHg of sensed pressure OR Press and hold 'DEFLATE' for 2 seconds to deflate the cuff. Alarm will stop automatically whenever the unit can regulate the cuff to within 15 mmHg of the pressure set point.

Condition	Description	Message display (steady)	Alarm tone	Pressure display	Time display	Action to silence alarm tone for 30 seconds	Action required to correct alarm condition
Tourniquet time exceeded	The unit's elapsed timer, which advances when the cuff is inflated, has reached the time limit set point and caused the time alarm to activate.	TIME LIMIT	Constant	Normal	Current tourniquet time, flashing	Momentarily Press 'PRESSURE + ', 'PRESSURE – ', 'TIME + ', or 'TIME – '.	Press and hold 'TIME + ' to increase time limit set point, OR Press and hold 'DEFLATE' for 2 seconds to deflate the cuff.
Battery Low (stage 1)	The battery voltage has dropped to a level indicating that the unit should be plugged into AC power for continued use, and to charge the battery.	BATT LOW 2 segments darkened in battery indicator symbol.	Cycle 1s on / 10s off	Normal	Normal	Momentarily Press 'PRESSURE + ', 'PRESSURE – ', 'TIME + ', or 'TIME – '.	Plug in AC power OR Press 'ON/STANDBY' to shut unit down.
Battery Low (stage 2)	The battery voltage has dropped to a level indicating that the unit may trigger a "BATT ERROR" alarm (see below) and shut down at any time.	BATT LOW 1 segment darkened in battery indicator symbol.	Constant	Normal	Normal	Momentarily Press 'PRESSURE + ', 'PRESSURE – ', 'TIME + ', or 'TIME – '.	Plug in AC power immediately OR Press 'ON/STANDBY' to shut unit down.
Battery Failure	The battery voltage has dropped below the threshold of safe operation and has shut down in a safe state* OR The battery has been removed/disconnected.	BATT ERROR Battery indicator symbol empty.	Constant	"Err"	Blank	None	Press 'ON/STANDBY' to shut unit down. When cuff deflation is required, disconnect hose to cuff. Ensure that the battery is connected properly. Plug in AC power to attempt to recharge the battery. Service or replace the battery pack (see Section 3.5 below).

Condition	Description	Message display (steady)	Alarm tone	Pressure display	Time display	Action to silence alarm tone for 30 seconds	Action required to correct alarm condition
Attempt to power off unit with cuff press-urized	The unit has detected that the operator has attempted to set the unit to standby with pressure remaining in the cuff.	CUFF NOT DEFLATED	Constant while button held, and for 2 seconds after button released.	Current cuff pressure, flashing	Normal	Momentarily Press 'PRESSURE + ', 'PRESSURE – ', 'TIME + ', or 'TIME – '.	Press and hold 'DEFLATE' for 2 seconds to deflate the cuff, then press 'ON/STANDBY' to shut unit down.
Cuff pressuri-zed during power up	The unit has detected an approximate pressure of 50mmHg or more in the cuff when the unit was powered up. The unit assumes a procedure is in progress, changes the pressure set point to the detected pressure, immediately regulates the cuff to this pressure, and activates alarm to alert the user of the condition.	PRESSURE	Constant	Current cuff pressure, flashing	Normal	Momentarily Press 'TIME + ' or 'TIME – '.	Momentarily press 'PRESSURE + ' or 'PRESSURE – ' button to display pressure set point OR Adjust pressure set point by pressing and holding 'PRESSURE + ' or 'PRESSURE – '.
Cuff not fully deflated	The unit has detected pressure in the cuff greater than 15mmHg, 60 seconds after the cuff has been deflated.	CUFF NOT DEFLATED	Constant	Current cuff pressure, flashing	Normal	Momentarily Press 'PRESSURE + ', 'PRESSURE – ', 'TIME + ', or 'TIME – '.	Disconnect hose to cuff to exhaust pressure.

Condition	Description	Message display (steady)	Alarm tone	Pressure display	Time display	Action to silence alarm tone for 30 seconds	Action required to correct alarm condition
Leak in cuff or hose	The unit has detected a large leak in a cuff defined as the cuff failing to reach the pressure set point in a reasonable time, or the pump running excessively while regulating in 'Inflating' or 'Regulating' mode and the pressure set point is not being adjusted.	CUFF LEAK (may also display PRESSURE LOW)	Constant	Current cuff pressure, flashing	Normal	Momentarily Press 'PRESSURE + ', 'PRESSURE – ', 'TIME + ', or 'TIME – '.	Fix leak OR Reduce pressure set point until unit can maintain pressure OR Press and hold 'DEFLATE' for 2 seconds to deflate the cuff.
Calibration failure	The unit has detected that the calibration in the pressure transducer is invalid. The unit has shut down in a safe state*. (See also Calibration Procedure, Section 3.3)	ERROR	Constant	"CAL"	"Err"	None	Disconnect the hose and press 'ON/STANDBY' twice to shut unit down and restart OR Calibrate the unit per Section 3.3
Internal electronic failure	The unit has detected an internal error and has shut down in a safe state*.	ERROR	Constant	"Err"	Error code	None	Press 'ON/STANDBY' twice to shut unit down and restart. When cuff deflation is required, disconnect hose to cuff.

*** In the 'safe state' mode, the current pressure in the cuff is held (in the absence of leaks). The 'safe state' mode helps prevent unexpected loss of occlusion during a procedure if a sudden failure occurs. See Section 2.8.2 for more detail.**

2.8.1 ALARM SILENCE FUNCTIONS

Most audible alarm tones may be silenced for 30 seconds by momentarily depressing the 'PRESSURE + ', 'PRESSURE – ', 'TIME + ', or 'TIME – ' button. At the end of the silenced period, the alarm tone will restart if the alarm condition has not been corrected. The alarm tone may be silenced for additional 30 second periods as required.

2.8.2 INTERNAL HARDWARE FAILURES

When "Err" and a numeric error code or "CAL" and "Err" appear in the pressure and time displays during use or power-up, an internal hardware failure has likely occurred and the P.T.S. unit is unusable. In this situation, it is likely that the unit has put itself in the 'safe state' mode, in which the pneumatic valve and pump are disabled and the current pressure in the cuff is held (in the absence of leaks). It is also likely that a tone will sound under these conditions. The 'safe state' mode helps prevent unexpected loss of occlusion during a procedure if a sudden failure occurs.

Although it is very unlikely, internal hardware failures may also cause erratic operation and/or unintelligible displays with or without alarms, and may or may not put the P.T.S. in the 'safe state' mode.

If either type of error occurs:

a) Set the unit to standby by pressing the 'ON/STANDBY' button. This removes power from the internal instrument circuitry and all instrument functions, causing the cuff to hold pressure (in the absence of leaks).

b) If required, attempt to restart the unit by pressing the 'ON/STANDBY' again to restart the unit.

c) If required to continue the procedure, clamp the hose with a hemostat to maintain cuff pressure, then immediately disconnect the faulty P.T.S. unit and connect a replacement unit.

d) If cuff deflation is required, disconnect the cuff from the P.T.S. unit.

WARNING: In all cases of internal hardware failure, erratic operation, or unintelligible displays, it is possible that the pressure in the cuff is not accurately displayed on the P.T.S. unit and that cuff pressure may be present even when the P.T.S. unit appears to be shut down. The user must immediately determine if the cuff is inflated or deflated and continually monitor the cuff to ensure patient safety. If deflation of the cuff is necessary, disconnect the hose from the P.T.S. unit or from the cuff and confirm that the cuff deflates completely.

2.8.3 PRESSURE HIGH or LOW ALARMS

A "PRESSURE HIGH" or "PRESSURE LOW" alarm will occur when the pressure in a cuff is more than 15 mmHg from the pressure set point. To minimize nuisance alarms that can be caused by vigorous movement of the patient's limbs, a 1 second delay has been designed into alarm actuation for these conditions.

2.8.4 LEAK ALARMS

It is possible for the system to have a substantial leak that the unit can compensate for by continual pumping. This type of leak could be due to a hole in the cuff or hose assembly, a loose or worn hose connector, or leaks in the pneumatic circuit inside the P.T.S. unit. All leaks require immediate attention, because they could progress into a total failure of a cuff to hold pressure at any time. To alert the operator that a substantial leak is present, the "CUFF LEAK" alarm is activated when this type of leak is continuously present for more than 7 seconds, even if the unit is maintaining the cuff pressure within 15 mmHg of the set point. If a "CUFF LEAK" alarm occurs, the cuff, hose assembly, and hose connectors should be checked for leaks. If an external leak cannot be found, test the P.T.S. unit per Section 3.4 below.

SECTION 3.0: P.T.S. MAINTENANCE INSTRUCTIONS

3.1 GENERAL MAINTENANCE INFORMATION

While the P.T.S. has been designed and manufactured to high industry standards, it is recommended that periodic inspection, testing, and calibration ('maintenance') be performed as described in this section to ensure continual safe and effective operation. This section also serves as a guide to troubleshooting and expediting unscheduled maintenance. The maintenance intervals listed below are provided as a guideline; refer also to the policies in your practice setting for general tourniquet maintenance procedures and intervals.

CAUTION: Do not attempt to disassemble or open the enclosure of your P.T.S. unit. The P.T.S. is not designed to be disassembled and serviced by anyone other than Delfi staff. Disassembly and attempted service by anyone other than Delfi staff poses a risk of electric shock, damage to the unit, and injury to the patient and will void all warranties. Internal parts in the P.T.S. can only be serviced at the factory by Delfi staff. Please contact Delfi if you have problems with your P.T.S. unit that cannot be resolved by following the maintenance and troubleshooting procedures described below.

3.2 PERIODIC MAINTENANCE

3.2.1 CLEANING

The exterior of the unit may be cleaned as often as required with a cloth that has been dampened (not dripping) with a mild detergent. The exterior of the cuff hose may be cleaned using a mild detergent solution or alcohol. Tourniquet cuffs should be cleaned in accordance with the manufacturer's instructions.

CAUTION: Do not attempt to clean or flush out the interior of the hose assembly. Do not allow fluids or debris to enter the hose connectors on the P.T.S. unit or the hose assembly.

CAUTION: Avoid exposing the AC power supply to liquids. Do not immerse in fluid. Do not allow the AC power supply to lie on the floor where pooling of liquids may occur. Clean by damp cloth (alcohol or mild detergent wipe) only. The AC power supply is resistant to occasional splashing or dripping of fluids, but is not fluid-tight. If immersed in or exposed to excessive amounts of liquids, the AC power supply may fail and may pose an electrical shock hazard.

3.2.2 INSPECTION

The unit should be externally inspected as follows at least once every three months:

- Obvious external damage.
- Missing or illegible labels and warnings.
- Kinks or damage in the power cord.
- Secure connection and locking of the power cord plug to the receptacle on the P.T.S. unit.
- Secure connection and locking of the hose connectors on the P.T.S. unit to the hose assembly.
- Kinks or damage in the hose assembly.

3.2.3 FUNCTIONAL AND CALIBRATION CHECKS

The functional and calibration checks described in Section 2.5 should be performed at least once every three months.

3.3 CALIBRATION

Calibration should be performed every six months, or after any unscheduled maintenance.

Calibration of the P.T.S. allows the output signal from the pressure transducer to be compared against a calibrated pressure source. The difference between the known pressure and the pressure measured by the

transducers is recorded at each of four set points, and these four calibration factors are used to correct the signal from the pressure transducers during normal operation. The calibration factors are stored in memory.

EQUIPMENT REQUIRED:

- Calibrated 0 to 500 mmHg pressure gauge.
- Adjustable 0 to 500 mmHg pressure source.
- Suitable pneumatic hoses and connectors.

CAUTION: The following steps must be taken in the exact order to calibrate the unit. Failure to do so may result in incorrect pressure readings while the unit is in operation.

a) To enter the calibration mode, press and hold the 'INFLATE' and 'DEFLATE' buttons simultaneously, then press 'ON/STANDBY' to switch the unit on. When the unit finishes its start-up sequence the unit will enter the calibration mode and display "0" in the pressure display and alternating "CAL" and "0" in the time display. This is to indicate to the user that the unit is now ready to calibrate. The time display indicates the expected reference pressure to be applied to the cuff. The pressure display indicates the sensed pressure.

b) With the hose connector on the P.T.S. unit open to atmosphere, press the 'PRESSURE + ' button to indicate zero reference pressure is applied. The unit will adjust the transducer output corresponding to zero pressure. The unit will then sound a tone to indicate that the reference pressure was taken.

c) Once the zero point is calibrated, press the 'TIME+ ' button to advance the unit to the next pressure level. The time display will now be alternating between "CAL" and "50". Connect the P.T.S. to the reference pressure source and gauge. Apply a calibrated reference pressure of 50 +/- 1 mmHg to the cuff port. Once the pressure has stabilized, press the 'PRESSURE + ' button to indicate the reference pressure is applied. The unit calibrates the 50mmHg point and sounds a tone when successfully completed. If the reference pressure is more than 15 mmHg different from the sensed pressure, the unit shows "CAL" and "Err" messages in the pressure and time displays respectively and halts the calibration routine. If this happens, power off the unit and start over.

d) Repeat the preceding step for reference pressures of 250 +/- 1 mmHg and 475 +/- 1 mmHg. The unit will not allow calibration points to be skipped.

e) Remove the reference pressure source and press the 'TIME- ' button three times to cycle the reference pressure back to zero. The time display will alternate between "CAL" and "0". Press the 'INFLATE' and 'DEFLATE' buttons simultaneously to exit the calibration. The unit saves the new calibration values in memory and displays "CAL" in both displays. Power off the unit by pressing the 'ON/STANDBY' button.

3.4 LEAK TESTING

Leak testing should be performed at least once every six months, or if leak alarms occur without an obvious cuff or hose leak. The P.T.S. is capable of maintaining cuff pressure even with a substantial leak in the system; however any leak may become worse and lead to loss of occlusion during a procedure, so it is important to find and correct leaks as soon as possible.

a) Connect a leak-free Delfi Contour Lower Leg cuff, Contour Arm cuff, or a similar sized cuff to the P.T.S. using the hose assembly.

b) Adjust the pressure set point to 475 mmHg.

c) Inflate the cuff and allow the pressure to stabilize.

d) Set the unit to standby as follows: Press the 'ON/STANDBY' button until the alarm message "CUFF NOT DEFLATED" appears. Release the 'ON/STANDBY' button and within 5 seconds of the alarm discontinuing, press and hold the 'ON/STANDBY' button again. Hold the button in for 10 seconds. The unit will switch to standby. **NOTE: During the 10 seconds, the alarm message will be displayed, the alarm will continue to sound and cannot be silenced.**

e) Wait for 10 +/- 1 minutes and turn the unit back on. Operation will resume with a "PRESSURE" alarm (See 'Cuff pressurized during power up' condition, Table 2.1). Momentarily press and release the 'PRESSURE+ ' button to cancel the alarm and display the new pressure set point (shown with a trailing asterisk). The set point should be at least 400 mmHg.

f) If the new set point is less than 400 mmHg, there is a significant leak in either in the test cuff and hose or in the P.T.S. internal pneumatics. Repeat the test with a variety of different cuffs and hose assemblies. If the unit continues to fail, the leak is internal and the P.T.S. unit must be serviced by Delfi.

3.5 BATTERY TESTING and REPLACEMENT

CAUTION: Risk of electric shock. Set the P.T.S. unit to standby and disconnect AC power before opening the battery compartment.

NOTE: It is recommended that the battery in the P.T.S. be tested as described below every 3 months and replaced annually. Even when the P.T.S. is used on AC power, the battery pack must be in good condition to provide backup power in the event of the AC power being disconnected. If the battery pack is removed or in poor condition, the P.T.S. will not operate (even with AC power connected) and a "BATT ERROR" alarm will be triggered upon power-up.

A new battery pack is designed to run the P.T.S. without AC power for about 10 hours of typical use on a full charge, however this charge life will vary greatly depending on the conditions of use. The life and performance of the battery pack also depends on the conditions of use and storage. Battery replacement will need to be more frequent with continued cycles of deep discharge and/or storage at high temperatures. Infrequent short-term use of the battery and storage at room temperature or lower will result in maximum life.

The P.T.S. features automatic battery charging and monitoring functions and attempts to charge the battery whenever the unit is connected to AC power, both in on and standby modes. No maintenance is required of the battery charging circuit. To check the charge level in the battery, the P.T.S. must be on with no AC power connected. When on under battery power, the battery indicator symbol appears in the message display (see Fig. 2.1). When all six segments inside the battery symbol are darkened, the battery has a full charge. Reducing numbers of darkened segments and low battery alarm conditions (see Table 2.1) progressively indicate decreasing battery capacity and need for recharging.

3.5.1 BATTERY TESTING

To determine if the battery pack needs replacement, charge it for at least 8 hours and then test as follows:

a) Remove the AC power supply and power up the P.T.S. unit. The battery indicator symbol should be visible in the message display and all 6 segments in the battery outline should be darkened.

b) Connect the P.T.S. to a tourniquet cuff and inflate to 350 mmHg.

c) If less than 5 segments in the battery indicator are darkened after 1 hour, replace the battery pack.

The battery pack must also be replaced if a "BATT ERROR" alarm condition occurs (see Table 2.1) that cannot be corrected by plugging the P.T.S. unit into AC power or by confirming that the battery pack is securely connected. You may also wish to replace the battery pack if you regularly use your P.T.S. on battery power and have "BATT LOW" alarm conditions occurring soon after a full charge.

3.5.2 BATTERY PACK REPLACEMENT

WARNING: Use only Delfi REF 4-2100-017 NiMh battery packs. Do not use any other batteries. Use of improper batteries may cause irregular operation that could be hazardous to the patient and/or user, and may permanently damage the P.T.S. unit.

WARNING: When a new battery pack is installed, the P.T.S. must be plugged in to AC power for at least 8 hours to fully charge the new battery before use.

a) Remove the single battery cover screw from the back of the P.T.S. unit (directly above the label) and remove the battery cover.

b) Remove the old battery pack and unplug it by pulling the battery wires straight up from the battery compartment. This will disconnect the battery connector from the two-pin plug inside the P.T.S. unit. **Recyle or dispose of the old battery pack in accordance with local regulations and procedures.**

c) Install the new battery pack supplied by Delfi by pushing the connector onto the two-pin plug inside the P.T.S. unit. Push the connector all the way down until it stops. The top of the connector will be about flush with the battery compartment surface. The connector cannot be installed the wrong way; if it will not slide easily all the way down, rotate it one-half turn and try again.

3.6 TROUBLESHOOTING GUIDE

Table 3.1 lists a number of possible malfunctions and their most likely causes. While it is not possible to list every conceivable malfunction and possible causes, the table will help the user solve the most common problems.

Table 3.1: Troubleshooting

MALFUNCTION	POSSIBLE CAUSES	CORRECTIVE ACTIONS
Unit does not turn on (with no AC power connected).	**Battery pack not charged.**	**Plug in to AC power and allow battery to charge. Attempt to turn unit on with AC power (see "BATT ERROR" alarm below).**
	Battery pack disconnected.	**Remove battery cover and ensure battery pack is securely plugged in.**
Unit does not turn on (with AC power connected).	**Internal hardware failure. Defective AC adapter/cord assembly.**	**Contact Delfi.**
Cuff does not inflate.	**Internal hardware failure.**	**Contact Delfi.**
Cuff does not deflate.	**'DEFLATE' button not held for 2 seconds.**	**Press and hold the 'DEFLATE' button for at least 2 seconds.**
	Hose kinked or blocked.	**Unkink hose or disconnect cuff from hose. Ensure complete cuff deflation to clear "CUFF NOT DEFLATED" alarms.**
	Internal hardware failure	**Contact Delfi.**
Green AC indicator light does not illuminate when unit is plugged in to AC power.	**AC power supply assembly not plugged in to suitable wall outlet.**	**Ensure wall socket is working, of the correct voltage, and that the plug is all the way in.**
	AC power supply assembly not plugged in to P.T.S. unit.	**Ensure connectors are fully engaged (audible 'click' heard when properly connected).**
	Incorrect AC power supply assembly.	**Ensure AC power adapter is the one supplied with the P.T.S. unit.**
	AC power supply not working	**Contact Delfi.**
	AC indicator light not working.	**Contact Delfi.**

MALFUNCTION	POSSIBLE CAUSES	CORRECTIVE ACTIONS
Red Alarm indicator light does not illuminate during alarm conditions.	**Alarm indicator light not working.**	**Confirm that alarm indicator light illuminates during self-check upon power-up. Contact Delfi.**
No cuff pressure and/or tourniquet time reading.	**Faulty pressure/time display.** **Internal hardware failure.**	**Confirm that all segments of the display illuminate during self-check upon power-up.** **Contact Delfi.**
Pump runs continuously.	**External leak (cuff or hose).** **Internal leak.** **Internal hardware failure.**	**Correct leak to clear leak alarm.** **Test for leaks (see Section 3.4 above).** **Disconnect P.T.S. from cuff to deflate cuff if required. Contact Delfi.**
BATT ERROR alarm.	**Fully discharged battery** **Battery pack disconnected.** **Faulty or dead battery pack.**	**Connect to AC power and allow battery to recharge for 8 hours.** **Remove battery cover and ensure battery pack is securely plugged in.** **Replace battery pack (see Section 3.5 above).**
Battery does not charge when unit is plugged in to AC power.	**Faulty or dead battery pack.**	**Replace battery pack (see Section 3.5 above).**
Unit does not turn off (cannot be set to standby)	**Pressure in cuff** **Internal hardware failure**	**Deflate cuff and ensure it deflates fully (disconnect hose if required) to clear "CUFF NOT DEFLATED" alarm.** **Contact Delfi. Unit can be powered off by unplugging the AC power and removing the battery pack (see Section 3.5).**

3.7 INTERNAL HARDWARE SERVICING

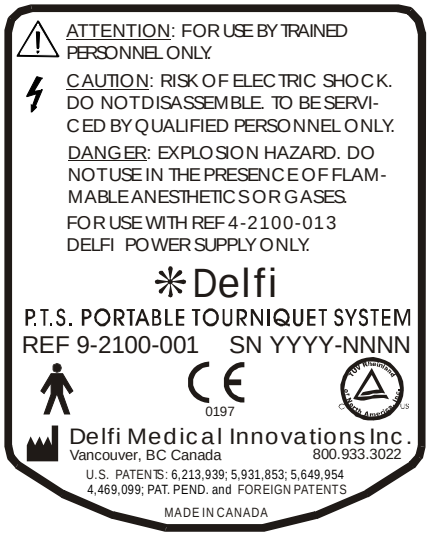
The P.T.S. is designed with self-test and self-monitoring features to warn of failures (see Table 2.1). Although it is very unlikely, modes of failure may also occur that cause erratic operation and/or illegible displays and may or may not trigger alarms. If the maintenance, calibration, and troubleshooting procedures described above do not restore normal operation, contact Delfi for service advice.

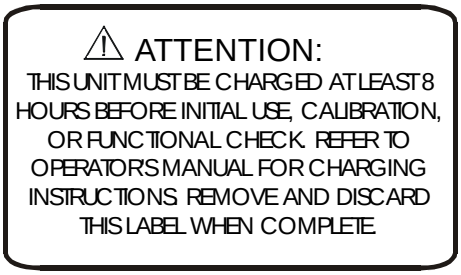
CAUTION: Do not attempt to disassemble or open the enclosure of your P.T.S. unit. The P.T.S. is not designed to be disassembled and serviced by anyone other than Delfi staff. Disassembly and attempted service by anyone other than Delfi staff poses a risk of electric shock, damage to the unit, and injury to the patient and will void all warranties. Internal parts in the P.T.S. can only be serviced at the factory by Delfi staff. Please contact Delfi if you have problems with your P.T.S. unit that cannot be resolved by following the maintenance and troubleshooting procedures described above.

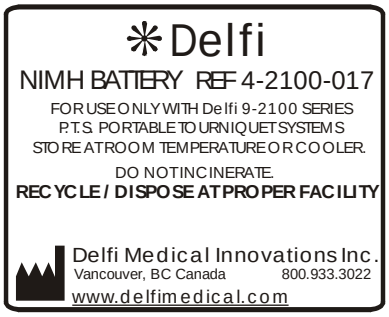
3.8 WARNINGS, CAUTIONS, LABELS, and SYMBOL DEFINITIONS

	Type B Medical Equipment		Earth ground
	Refer to operator and maintenance manual	~	Alternating Current
	Electrical hazard: Dangerous voltage	⎓	Direct current
CE	Conformity marking of the Council of the European Community		
TÜV Rheinland cTÜVus	cTUVus: Medical Equipment with respect to electrical shock, fire and mechanical hazards and electromagnetic compatability only in accordance with CAN/CSA – C22.2 No.601.1-M90, and UL 2601-1		
EC REP	Authorized representative in the European Community		
	Manufacturer name and adress		

Figure 3.1: Labels







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